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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,176	01/12/2004	Mark B. Knudson	14283.1US17	2095

7590 06/12/2006

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EXAMINER

REIDEL, JESSICA L

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/756,176	Applicant(s) KNUDSON ET AL.	
	Examiner Jessica L. Reidel	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 11-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>02/04 01/04 01/04 03/04 09/04 01/06</u> | 6) <input type="checkbox"/> Other: _____ |
| <u>06/06 08/06 02/06</u> | |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Claims 1-10 in the reply filed on May 24, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on February 24, 2004, April 12, 2004, July 19, 2004, August 6, 2004, September 27, 2004, January 21, 2005, May 26, 2005, August 31, 2005 and February 2, 2006 have been acknowledged and are being considered by the Examiner.

3. The information disclosure statements filed February 24, 2005 and May 26, 2005 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Both have been placed in the application file, but the information referred to therein has not been considered.

Specification

4. The abstract of the disclosure is objected to because the content is no longer representative of Applicant's invention due the withdrawal of Claims 11-31. The Examiner

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suggests omission of the phrase “and apparatus” at the first line of the Abstract. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wernicke et al. (U.S. 5,263,480) (herein Wernicke ‘480) in view of Cohen et al. (U.S. 6,684,105) (herein Cohen). As to Claims 1-4 and 7, Wernicke ‘480 discloses a method of treating patients with eating disorders by use of a therapy which alleviates a symptom of the disorder, which comprises the steps of responding to a specific eating disorder of interest (i.e. obesity, bulimia or anorexia nervosa) by applying a predetermined stimulating signal to the patient’s vagus nerve 44 appropriate to alleviate the symptom of the disorder of interest (see Wernicke ‘480 Abstract, column 1, lines 10-19 and lines 50-62, column 3, lines 55-68, column 4, lines 1-25 and lines 47-59, column 5, lines 13-36 and lines 48-68, column 6, lines 1-46, column 8, lines 32-46 and lines 63-67, column 10, lines 33-68 and column 12, lines 14-54). Wernicke ‘480 discloses the claimed invention as discussed above except that the method does not include the steps of applying a neural conduction block to the vagus nerve at a blocking site with the neural conduction block selected to at least partially block nerve impulses on the vagus nerve at the blocking site.

Cohen, however, discloses an apparatus and methods for treatment of a plurality of disorders by unidirectional nerve stimulation in order to minimize possible accompanying side effects of the stimulation treatment (see Cohen Abstract and column 1, lines 6-11). Cohen expressly discloses that an object of the invention is “to provide apparatus and methods for treatment of eating disorders, while minimizing adverse side effects caused by stimulation of the nerves controlling the digestive system” (see Cohen column 4, lines 14-23 and lines 31-35). Cohen further discloses that the apparatus and method applies a neural conduction block to a vagus nerve at a blocking site with the neural conduction block selected to at least partially block nerve impulses on the vagus nerve at the blocking site and that the block is applied to the nerve between a location of application of a stimulating signal and an organ to be shielded from adverse effects of the stimulation signal (see Cohen column 4, lines 54-63 and column 6, lines 38-67).

Cohen also specifies that the stimulation driving current and the suppressing of the action potentials in an opposite direction (i.e. blocking) is preferably performed at the same time (see Cohn column 6, lines 65-67) and that characteristics of the electrical conductive block are variable by a controller 50 (see Cohen column 7, lines 54-65, column 8, lines 6-21 and lines 30-62). Cohen expressly discloses that the apparatus and associated methods may be used in conjunction with those of Wernicke ‘480 (see Cohen column 5, lines 20-39). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Wernicke ‘480 in view of Cohen to include the steps of applying a neural conduction block to the vagus nerve at a blocking site between a location of application of a stimulation signal and an organ to be shielded, with the neural conduction block selected to at

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least partially block nerve impulses on the vagus nerve at the blocking site in order to better the invention.

7. As to Claim 8, Wernicke '480 expressly discloses that the method comprises detecting a preselected event (i.e. sum of total swallows in a predetermined period of time exceeding a threshold) via sensing electrodes 12-1 and 12-2 indicative of an imminent need for treatment of the specified eating disorder of interest (i.e. over consumption of food) and the responding includes responding to the detected occurrence by applying stimulation to the vagus nerve 44 via electrodes set 40 (see Wernicke '480 Abstract, column 5, lines 27-28 and lines 48-68, column 6, lines 1-9 and lines 35-46, column 8, lines 32-46 and column 10, lines 33-68).

8. As to Claim 9, Wernicke '480 expressly discloses that the disorder of interest is compulsive eating to excess and that the stimulation signal is predetermined to produce a sensation of satiety in the patient (see Wernicke '480 Abstract, column 4, lines 47-51, column 5, lines 48-68, column 6, lines 1-9, column 11, lines 49-61 and column 13, lines 45-64).

9. As to Claim 10, Wernicke '480 expressly discloses that the stimulation signal is applied to the patient's vagus nerve 44 by a nerve electrode set 40 implanted on the nerve 44 in the vicinity of the patient's stomach 13 (see Wernicke '480 Figs. 2-4, column 5, lines 62-65, column 6, lines 7-9 and column 12, lines 14-53).

10. As to Claims 5 and 6, the previously modified Wernicke '480 reference discloses the claimed invention as discussed above except that it is not specified that the neural block be a cryogenic block or a pharmacologic block. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method as taught by Wernicke '480 in view of Cohen with either a cryogenic block or a pharmacologic block, because Applicant has

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not disclosed that cryogenic blocks or pharmacologic blocks provide an advantage, are used for a particular purpose or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrical conductive block as taught by Cohen, because it provides a means for unidirectional nerve stimulation to treat an eating disorder of interest while avoiding adverse side effects and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Wernicke '480 in view of Cohen.

Therefore, it would have been an obvious matter of design choice to modify Wernicke '480 in view of Cohen to obtain the invention as specified in the claim(s).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-13 and 16 of copending Application No. 10/674,324 in view of Wernicke '480. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the claims of Application No. 10/674,324 or an obvious variant thereof. Specifically, the claims of Application No. 10/674,324 include all of the limitations of the current claims except it is not specified that the method include "responding to a specified eating disorder of interest". Wernicke '480, however, expressly discloses that the method comprises detecting a preselected event (i.e. sum of total swallows in a predetermined period of time exceeding a threshold) via sensing electrodes 12-1 and 12-2 indicative of an imminent need for treatment of the specified eating disorder of interest (i.e. over consumption of food) and the responding includes responding to the detected occurrence by applying stimulation to the vagus

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nerve 44 via electrodes set 40 (see Wernicke '480 Abstract, column 5, lines 27-28 and lines 48-68, column 6, lines 1-9 and lines 35-46, column 8, lines 32-46 and column 10, lines 33-68). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the claims of Application No. 10/674,324 to include such limitations in order to allow treatment to be applied to the patient when needed the most.

This is a provisional obviousness-type double patenting rejection.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Rubin et al. (U.S. 6,369,079) teaches that it is well known to use a pharmacologic block to treat obesity, irritable bowel syndrome and constipation.


Lin (U.S. 6,558,708) teaches that it is well known to use a pharmacologic or cryogenic block to treat obesity.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jessica L. Reidel 06/08/06
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Robert E. Pezzuto
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